

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JOHN HANCOCK LIFE INSURANCE
COMPANY, JOHN HANCOCK
VARIABLE LIFE INSURANCE
COMPANY and MANULIFE
INSURANCE COMPANY,

Plaintiffs,

v.

ABBOTT LABORATORIES,

Defendant.

CIVIL ACTION NO. 05-11150-DPW

**ABBOTT'S DEPOSITION DESIGNATIONS AND COUNTER DESIGNATIONS
FOR STANLEY BUKOFZER**

Defendant Abbott Laboratories (“Abbott”) respectfully submits the attached deposition designations and counter-designations for the May 9, 2007 deposition of Stanley Bukofzer, MBBCh., M.Med., former Head of the Anti-Infective Venture (ABT-773), former Head of the Anti-Infective Venture (ABT-773).

Dated: February 18, 2008

Respectfully submitted,

ABBOTT LABORATORIES

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CERTIFICATE OF SERVICE

I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on February 18, 2008.

Date: February 18, 2008.

/s/ Ozge Guzelsu

Stanley Bukofzer Deposition Designations

Date	Witness	Hancock Desig	Abbott Counter Desig	Abbott Desig	Hancock Counter Desig	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
5/9/07	Bukofzer, Stanley	15:24-16:6						
5/9/07	Bukofzer, Stanley	56:2-56:22						
5/9/07	Bukofzer, Stanley	57:2-57:15						
5/9/07	Bukofzer, Stanley		57:15-57:17					
5/9/07	Bukofzer, Stanley	72:10-72:18						
5/9/07	Bukofzer, Stanley		72:19-73:13					
5/9/07	Bukofzer, Stanley	73:14-73:23						
5/9/07	Bukofzer, Stanley		73:24-74:6					
5/9/07	Bukofzer, Stanley	78:6-78:13						
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5/9/07	Bukofzer, Stanley	166:15-166:21				9	IM	
5/9/07	Bukofzer, Stanley		166:23-167:4					
5/9/07	Bukofzer, Stanley		168:3-168:12					
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5/9/07	Bukofzer, Stanley		169:7-169:17					
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5/9/07	Bukofzer, Stanley		174:1-174:17					
5/9/07	Bukofzer, Stanley		175:7-175:13					
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	Stanley		176:8					
5/9/07	Bukofzer, Stanley	223:1- 223:10				13	JA	
5/9/07	Bukofzer, Stanley	226:19- 227:6				13	JA	
5/9/07	Bukofzer, Stanley		227:7- 228:2					
5/9/07	Bukofzer, Stanley	295:10- 295:17				23	QM	
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5/9/07	Bukofzer, Stanley	300:14- 300:19				23	QM	
5/9/07	Bukofzer, Stanley		300:20- 301:1					
5/9/07	Bukofzer, Stanley	301:2- 301:12				23	QM	
5/9/07	Bukofzer, Stanley		301:13- 301:17					
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5/9/07	Bukofzer, Stanley	325:16- 328:7				23	QM	

Color Key to Deposition Designations

Designation by Plaintiffs

Counter Designation by Defendants

Designation by Defendants

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1 THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS
3 JOHN HANCOCK LIFE INSURANCE)
4 COMPANY, JOHN HANCOCK VARIABLE)
5 LIFE INSURANCE COMPANY, and)
6 MANULIFE INSURANCE COMPANY)
7 (f/k/a INVESTORS PARTNER) Civil Action
8 INSURANCE COMPANY),) No.
9 Plaintiffs,) 05-11150-DPW
10 -vs-)
11 ABBOTT LABORATORIES,)
12 Defendant.)
13

14 The videotaped deposition of
15 STAN BUKOFZER, M.B., B.Ch., M.Med., called as a
16 witness herein for examination, taken pursuant to
17 the Federal Rules of Civil Procedure of the United
18 States District Courts pertaining to the taking of
19 depositions, taken before ROSANNE M. NUZZO, a
20 Notary Public within and for the County of Will,
21 State of Illinois, and a Certified Shorthand
22 Reporter of said state, at Suite 1300, Two North
23 LaSalle Street, Chicago, Illinois, on the 9th day
24 of May, A.D. 2007, at approximately 9:06 a.m.

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1 And my postgraduate degree, I don't
2 recall if it was 1986 or 1987. I'd have to just
3 check on the certificate. It's some years back.

4 Q. You testified that you became head of
5 the Anti-infective Venture in approximately
6 April 2001, correct?

7 A. Correct.

8 Q. What were your responsibilities as head
9 of the Anti-infective Venture?

10 MR. PHILLIPS: Over -- at that time or
11 overall, over the entire period?

12 MR. ZWICKER: Well, let's take the period
13 from 2001 to 2002.

14 THE WITNESS: Okay.

15 BY THE WITNESS:

16 A. My spec- -- well, there were two
17 compounds that we had in development at that
18 particular time that I was responsible for. The
19 one compound was ABT-773, and the other compound
20 was a quinolone compound.

21 BY MR. ZWICKER:

22 Q. Was that ABT-492?

23 A. 492, correct.

24 Q. Is it fair to say that you were

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1 responsible, in your role as head of the

2 Anti-infective Venture, for the overall

3 development of ABT-773?

4 A. It was fair to say that my

5 responsibility was to lead a team that was

6 responsible for that development.

7 Q. You supervised that team?

8 A. I supervised the team.

9 Q. Is it fair to say that your supervision

10 of that team included supervising Abbott's efforts

11 to obtain FDA approval for 773?

12 A. Can you just repeat the question,

13 please.

14 Q. Sure. Is it fair to say that your

15 supervision of the 773 team included supervising

16 Abbott's efforts to obtain regulatory approval

17 from the FDA for 773?

18 A. Yes, to the extent that it was

19 possible. We -- my -- my specific direction was

20 to try and ensure that we could get the drug

21 approved. Obviously, one learns a lot about drugs

22 as you develop them, and -- but one's aim

23 throughout was to try and have the drug approved,

24 not only by the FDA, but by other agencies as well

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1 BY MR. ZWICKER:

2 Q. Did you come to believe that 773 would

3 have to demonstrate to the FDA -- strike that.

4 When you took over as venture head, did

5 you understand that there was an issue for 773

6 regarding the number of times per day it would be

7 dosed?

8 A. Yes.

9 Q. What did you understand that issue to

10 be?

11 A. As I understood it, that there was a

12 commercial imperative that had -- well, a

13 commercial imperative or a commercial wish that to

14 meet the market needs, it would be preferable to

15 have a once-daily dosing. It was not an absolute,

16 but it would certainly be a preference that the

17 commercial team had, to -- to have a once-daily

18 dose. They felt that a twice-daily dose would be

19 less commercially attractive.

20 Q. Once-daily dosing is known as

21 "QD" dosing --

22 A. Correct.

23 Q. -- is that right? Twice-daily dosing

24 is known as "BID" dosing?

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1 A. Correct.

2 Q. You said there was a preference for

3 once-a-day dosing. Was that across all

4 indications for 773 or just some?

5 A. As I recall, it was -- if I can just

6 step back and just expand on that, it was a

7 preference for the U.S. commercial team to have

8 once-daily dosing. The issue was not seen as

9 imp- -- as that important in the rest of the

10 world. In fact, in some parts of the world, such

11 as Japan, it was seen as preferable to have a more

12 frequent dosing.

13 So coming back to your specific

14 question for "all indications," I think that the

15 preference was there for all indications. But,

16 again, there was a rank order of which ones were

17 more important and which were less important.

18 Q. Dr. Bukofzer, when you became head of

19 the venture in April of 2001, was it your

20 understanding that the dosing decision was the

21 most important decision facing the successful

22 development of 773?

23 A. I don't think that that's characterized

24 correctly. I think it was one of the very

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1 150 milligrams, or the 300 milligrams could be a
2 QD or a BID dose.

3 There was -- there was no discussion at
4 that time, as I recall, that we were going to look
5 at a different total dosage. That work had taken
6 place prior to my joining the venture.

7 Q. And let me focus on the 150 milligram
8 QD dose.

9 A. Okay.

10 Q. When you took over the venture in
11 April 2001, did you understand that there were
12 obstacles to Abbott's achievement of a
13 150 milligram QD dose for 773?

14 A. My understanding at the time was that
15 there was not certainty around the -- around
16 whether the 150 milligram dose would reach the
17 necessary hurdles from an efficacy perspective but
18 that it certainly not excluded that it could.

19 And, therefore, the study that was
20 ongoing at the time that I took over was a
21 comparison in community-acquired pneumonia,
22 comparing the 150 milligrams daily to the
23 150 milligrams twice-daily dose, as I recall.

24 Q. So you understood that 150 milligrams

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1 dosed once a day might not be efficacious when you
2 took over the venture?

3 A. I think -- no, that's not correct.

4 That's not correct.

5 I understood that it might not meet
6 certain efficacy hurdles when comparing it against
7 the necessary comparators that we would have been
8 required to compare against. I felt -- I think
9 that it was thought that it would likely be
10 efficacious, but it's a question of reaching a
11 certain amount of effectiveness, compared to
12 another drug, that determines whether the agencies
13 feel it would be approvable or not.

14 Q. When you took over the venture in
15 April 2001, did you understand that there was
16 insufficient data to support an efficacy claim for
17 150 milligrams dosed once a day for 773?

18 A. There was insufficient data in that
19 time to support any dosing. What the -- that was
20 the reason for doing the trials that were
21 subsequently done. When one finishes Phase 2,
22 generally, you have a range of dosing that you can
23 choose from.

24 As I mentioned before, there is a

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1 risk/benefit of that drug -- or it's a
2 risk/benefit of a certain dose given in a certain
3 way that determines whether the drug is approvable
4 or not. That's the purpose of Phase 3 trials, to
5 do it in a patient population against a comparator
6 at a certain ...

7 MR. ZWICKER: Let's mark this as the next
8 exhibit.

9 MR. PHILLIPS: This is 4?

10 THE COURT REPORTER: Yes, sir.

11 MR. PHILLIPS: Is that correct? Thank you.
12 (WHEREUPON, said document was
13 marked Bukofzer Deposition Exhibit
14 No. 4, for identification, as of
15 5/9/07.)

16 THE WITNESS: Thank you.

17 MR. ZWICKER: Before the witness is Bukofzer
18 Exhibit No. 4, which is an ABBT -- ABT-773
19 Portfolio Review dated December 5th, 2000.

20 BY MR. ZWICKER:

21 Q. Dr. Bukofzer, could you look at the
22 document, and let me know when you're done
23 reviewing it.

24 A. Sure.

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1 insufficient data to support an efficacy claim at

2 once-a-day dosing at 150 milligrams?

3 A. No. I -- you need to be more specific.

4 Q. Let me ask you a different question.

5 A. Sure.

6 Q. Okay. Do you agree that at the time

7 you took over the venture, there was insufficient

8 data to support dosing once a day at

9 150 milligrams for certain indications of 773?

10 A. I think that there was an opinion by

11 many that it would be a -- more of a challenge to

12 achieve that, given the severity of these two

13 diseases.

14 I think it's important to understand

15 that generally, medically, CAP pneumonia,

16 community-acquired pneumonia, and ABS, acute

17 bacterial sinusitis, are generally considered more

18 significant diseases than bronchitis and

19 pharyngitis and, therefore, medically speaking,

20 people would prefer to have higher doses to be

21 more sure of total eradication.

22 Coming back to your specific question

23 that insufficient data exists, the data that

24 existed was the data from preclinical data and the

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1 Phase 1 and 2 trials. And as far as I remember,
2 the CAP and ABS indications had not been tested at
3 the 150 milligram dose, but I would have to
4 check -- I would have to go back and have a look
5 at what data actually existed at that time to be
6 sure.

7 Q. But you would agree with the -- with
8 the statement that as of the time you took over
9 the venture, the ability to achieve once-a-day
10 150 milligram dosing was uncertain, in part,
11 because of the limited amount of data available?

12 MR. PHILLIPS: Objection, compound.

13 BY THE WITNESS:

14 A. Can you -- I think that there were two
15 questions in there. Can you just break them out.

16 BY MR. ZWICKER:

17 Q. You would agree that at the time you
18 took over the venture, there was limited data
19 regarding efficacy for certain indications of 773
20 at 150 milligrams dosed once a day?

21 A. Some of the indications at that time
22 had not been tested at the 150 milligrams
23 once-a-day dose.

24 Q. And so that made the ability to achieve

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1 once-a-day dosing for those indications, at least

2 at the time you took over the venture, as

3 uncertain?

4 A. I don't know that you can say that it's

5 any more uncertain than any of the data that --

6 of -- any of the indications for which you had

7 data because, ultimately, the test to meet the

8 standard that had not been tested against.

9 Q. As of April 2001, when you took over

10 the venture, you didn't believe that Abbott could

11 say that it was likely that it could achieve

12 once-a-day dosing for all indications for 773,

13 correct?

14 A. No. That's not correct.

15 I think that there were a number of

16 decision analyses made at some -- at different

17 points, and I think -- I don't know whether there

18 was any decision analyses done prior to my being

19 head of the venture. But certainly, afterwards,

20 there were certain decision analyses made, at

21 which stage I don't even think at that time we

22 said it was not possible. I think there's just a

23 range of probabilities.

24 Q. Abbott eventually determines to go

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1 organism, MRSP and PRSP, as I recall, which we --
2 were the two organisms which were -- that were the
3 key organisms to obtaining the resistance claims.

4 Q. When you joined the venture, what was
5 your understanding of why Abbott wanted to obtain
6 a resistance claim for 773?

7 A. Part of the differ- -- it would be
8 partly to differentiate the drug from macrolide
9 antibodies. The spectrum of organisms that were
10 treated with this drug would be similar to the
11 spectrum that would be treated by macrolides.

12 However, if one could show that because
13 of its structure and that it had an additional
14 benefit to be able to treat organisms that
15 macrolides -- existing macrolides could not, it
16 would help differentiate the drug from -- from the
17 existing competition.

18 Q. And by differentiating the drug, you
19 believed, at the time you joined the venture, that
20 Abbott would have a commercial advantage over its
21 competitors?

22 A. Any time that you can get a claim that
23 differentiates a drug, it's helpful.

24 Q. Did you also believe that a resistance

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1 claim, at the time you joined the venture, would
2 increase the probability of FDA approval for 773?

3 A. I think that that was discussed at --
4 at a number of meetings.

5 Q. And the answer was "yes"?

6 A. Yes. I think that if you can show
7 that, it would always help.

8 Q. At the time you joined the venture,
9 were you aware that the FDA had expressed
10 skepticism regarding 773's ability to achieve a
11 resistance claim?

12 A. I was not specifically aware of that,
13 no. I think that in general, there was no
14 guidance documents on how to obtain a resistance
15 claim. A resistance claim, as I -- as I recall,
16 had only been given to one other quinolone in the
17 past. And some of the efforts that we undertook
18 were to try and understand what the level of data
19 was that had helped them get their resistance
20 claim, and I don't even recall which of the
21 quinolones it was.

22 What I do recall, it was a very small
23 number of organisms treated in the clinical -- in
24 the clinical trials. The problem for us was that

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1 it's -- there was no clear definition as to how
2 to -- you know, what -- what standard you would
3 have to meet to achieve that.
4 And so one was, in some ways, hoping
5 that if you exceeded what had been done in the
6 past, we could achieve the claim; in other words,
7 exceed the number of organisms and at least exceed
8 the rate of -- of resistance.

9 Q. You said that the problem was that at
10 the time you joined the venture, there was no
11 clear regulatory definition of the number of
12 isolates needed to achieve a resistance claim,
13 right?

14 MR. PHILLIPS: Objection, mischaracterizes
15 the testimony.

16 BY THE WITNESS:

17 A. I don't know my exact wording, and
18 I don't want to use the word "problem." The -- it
19 was a fact that one needed to -- there was no
20 clear pathway forward.

21 BY MR. ZWICKER:

22 Q. And because there was no clear pathway
23 forward, there was some uncertainty about whether
24 Abbott could achieve a resistance claim, correct?

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1 A. Not because there was no -- well, any
2 time that there's no absolute format to do it,
3 there would be some degree of uncertainty.
4 That didn't mean to say that the drug would not be
5 able to treat those organisms. It was a question
6 of whether or not the FDA and/or other agencies
7 would agree to put wording in the label to that
8 extent.

9 (WHEREUPON, a certain document was
10 marked Bukofzer Deposition Exhibit
11 No. 6, for identification, as of
12 5/9/07.)

13 THE COURT REPORTER: No. 6.

14 THE WITNESS: Thank you.

15 MR. ZWICKER: Before the witness is Bukofzer
16 Exhibit No. 6, which is a report regarding ABT-773
17 dated February 2001.

18 BY MR. ZWICKER:

19 Q. Dr. Bukofzer, if you could review
20 Exhibit No. 6 and let me know when you're done.

21 (Short pause.)

22 BY THE WITNESS:

23 A. Yes, I've looked at --

24 BY MR. ZWICKER:

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1 the probabilities of achieving a resistance claim?

2 A. I understood that that was one of the
3 ways that you might help achieve a resistance
4 claim.

5 Q. Can you explain to me why that is?

6 A. Yes. Because medically, if doctors
7 consider a patient to be bacteremic, which is
8 another -- which is the word for organisms
9 circulating in your blood -- sometimes, one calls
10 it septicemic -- patients would generally be
11 admitted to a hospital. And patients with
12 septicemia or bacteremia would generally be put
13 onto intravenous formulations rather than oral
14 formulations. That is just a general standard--
15 it's a generalization, but it's a general way that
16 doctors would respond to septicemic patients.

17 If a doctor -- so as -- and put another
18 way, that if a doctor knew a patient was
19 bacteremic, they would probably not choose to
20 treat them as an outpatient on oral therapy.

21 Q. When you joined the venture, did you
22 understand that Abbott had declined to fund an
23 IV formulation for 773?

24 A. I don't know that that is accurate.

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1 I -- what I learnt is that the IV formulation had
2 not been tested in man yet and that it was -- but
3 no one had said it would never be funded. I did
4 understand that the -- that funding up to that
5 stage had not been -- it hadn't been fully funded
6 or funded to an extent up to that stage. I knew
7 that. It wasn't that -- I don't know that there
8 was any decision never to fund an IV formulation.

9 Q. When you joined the venture, was it
10 your understanding that the -- an IV formulation
11 had not been fully funded? Did you understand
12 that?

13 MR. PHILLIPS: Objection, vague.

14 BY THE WITNESS:

15 A. Can -- can you be more specific,
16 please.

17 MR. PHILLIPS: Joe, we have been going for
18 about another hour. When you get to a convenient
19 stopping point, if we can take a very brief break.

20 MR. ZWICKER: Why don't we do that now.

21 MR. PHILLIPS: Are you sure? Is this a good
22 time? I don't --

23 MR. ZWICKER: Yeah.

24 MR. PHILLIPS: Okay.

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1 for the CAP indication, correct?

2 Let me ask you a different question.

3 As of February 2001, Abbott hadn't

4 decided the dosing level for the CAP indication?

5 A. "Dosing level" meaning?

6 Q. Once a day or twice a day.

7 A. For CAP, that's correct.

8 Q. Depending upon the outcome of the

9 clinical trials, did you understand that there

10 could be regulatory challenges with respect to

11 dosing at 150 milligrams once a day?

12 MR. PHILLIPS: Objection, vague as to what

13 you mean by "the clinical trials."

14 BY THE WITNESS:

15 A. Can you just specify which clinical

16 trials you --

17 BY MR. ZWICKER:

18 Q. Well, you just testified that --

19 A. There were ongoing clinical trials.

20 Q. -- there were ongoing clinical trials.

21 A. So, in regard to that, we would look at

22 the data and make a decision on the probabilities

23 of success; and given the data, the learnings

24 that -- from the data that existed.

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1 time you joined the venture, you didn't know
2 whether there would be a regulatory challenge
3 because you didn't know what the data was going to
4 show, correct?

5 A. We didn't know what the data was going
6 to show, and that was part of a decision analysis
7 that we were going to have to do when we received
8 that data.

9 We didn't know, based on what's written
10 here -- and I recall the AI person in regulatory
11 mentioning this -- that -- that because CAP was
12 considered a more serious disease, that regulators
13 in general in Europe would err on the side of
14 conservatism and want more drug than less drug.
15 That is just the way Europe tends to be,
16 particularly in the anti-infective area.

17 Q. So when you joined the venture in
18 April 2001, you didn't know whether CAP would be
19 dosed at QD or BID, correct?

20 A. I didn't know.

21 (WHEREUPON, a certain document was
22 marked Bukofzer Deposition Exhibit
23 No. 8, for identification, as of
24 5/9/07.)

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1 A. I don't. I don't have notes from --
2 from that meeting.

3 But I would have given him a very
4 effectual up-to-date update of the information
5 that I knew and would have told him what
6 information was forthcoming.

7 Q. Do you remember telling him at the time
8 that ABT-773 -- that its development had been
9 terminated?

10 A. I don't recall ever specifically saying
11 to him that it had been terminated because
12 I wasn't ever given -- certainly, not in the time
13 that I spoke to him -- instructions that it had
14 been terminated.

15 (WHEREUPON, a certain document was
16 marked Bukofzer Deposition Exhibit
17 No. 9, for identification, as of
18 5/9/07.)

19 MR. ZWICKER: The -- before the witness is a
20 document entitled "ABT-773 Descriptive Memorandum,
21 February 2001, Abbott Laboratories."

22 BY MR. ZWICKER:

23 Q. Dr. Bukofzer, could you review
24 Exhibit No. 9 and tell me if you recognize it.

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1 (Short pause.)

2 BY THE WITNESS:

3 A. Uh-uh. I don't specifically recognize

4 the context of this document.

5 BY MR. ZWICKER:

6 Q. Do you remember being called upon in

7 2001 to assist John Leonard or anyone else in

8 preparing a report regarding the status of 773?

9 A. Can you please be more specific.

10 Q. Yeah. Do you remember in 2001 being

11 asked by John Leonard or by anyone else to prepare

12 a status report for 773?

13 A. The -- I think I've testified earlier

14 that I think there were monthly status reports

15 that were sent out. I don't recall any other very

16 specific status report. I do know that I --

17 sorry. Can you -- can you just confirm, which

18 year are you talking about?

19 Q. 2001.

20 A. Oh, 2001. You know, the -- and there

21 were, I think, a number of presentations that

22 I gave to the PEC and senior management that would

23 have been in some way a status report of

24 whether -- where the drug -- you know, of issues

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1 or updates on the drug, but I don't recall a
2 specific report.

3 Q. You -- do you have any recollection of
4 being asked by John Leonard to provide input into
5 a document that was going to be used by a party
6 investing in 773?

7 A. No.

8 If I can just point out that this
9 document that you've just given me, document
10 No. 9, it's February of 2001, which would be just
11 in that sort of period ahead of me being involved
12 in the venture.

13 Q. If you could focus on page 2 of the
14 document.

15 A. I've got that.

16 Q. And look for now at the second
17 paragraph.

18 A. Okay.

19 Q. It says:

20 "Product features such as high
21 efficacy, activity against resistant
22 strains of bacteria and convenience
23 should enable it to" complete -- "to
24 compete against both Zithromax and

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1 newer agents such as the quinolones.

2 Dosing is expected to be once-a-day.

3 A 5-day convenience pak at a competitive

4 price will help maximize sales."

5 Do you see that?

6 A. I see what you're reading.

7 Q. Dr. Bukofzer, would you agree with me

8 that at the time you joined the venture in

9 April of 2001, that you personally did not have an

10 expectation that dosing for 773 for all

11 indications would be once a day?

12 A. No. I cannot say that. I -- I think

13 I've testified earlier that a QD dosing was

14 being -- well, the QD dosing was thought for the

15 two minor indications to be what we were

16 expecting; and the two major indications were

17 still being tested, a QD versus a BID.

18 Q. Well, so at the -- you've testified,

19 though, that at the time you joined the venture --

20 A. Um-hum.

21 Q. -- there was still testing going on

22 to determine what the appropriate dose would be,

23 correct?

24 A. Correct.

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1 answer.

2 MR. PHILLIPS: I'm not instructing --

3 THE WITNESS: No, not at all.

4 MR. PHILLIPS: I'm not instructing you not to
5 answer. I'm just -- I'm just making an objection
6 for the record.

7 THE WITNESS: So -- oh, I see. Okay. Thank
8 you.

9 BY THE WITNESS:

10 A. So the -- yes. We were awaiting to see
11 what the dose -- what -- what the outcome of the
12 trials would be. There was, as I said, a
13 preference by the commercial world to have a
14 QD dose.

15 BY MR. ZWICKER:

16 Q. But whether or not that was going to
17 happen was going to be a function of the results
18 you got from those trials, right?

19 MR. PHILLIPS: Objection, mischaracterizes
20 the testimony.

21 BY THE WITNESS:

22 A. This -- the trials would certainly have
23 been one of a number of data points to -- to be
24 considered.

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1 BY MR. ZWICKER:

2 Q. And at the time you joined the venture,

3 you didn't know what those results were, correct?

4 A. I couldn't have known the results. The

5 trials were ongoing.

6 Q. So you couldn't have had an

7 expectation, could you, that ABT-773 was going to

8 be dosed at once a day?

9 A. I could not have excluded that

10 possibility.

11 Q. But you couldn't have expected it,

12 either, correct?

13 A. No. I -- no. That's different. I --

14 I didn't have any --

15 MR. PHILLIPS: Are you talking -- excuse me.

16 Are you talking about all indications?

17 BY THE WITNESS:

18 A. Can you -- can you clarify? All

19 indications or one indication?

20 BY MR. ZWICKER:

21 Q. Well, let's start with all indications

22 for the moment.

23 A. Well, I think, to be fair, it's

24 probably the same. I had -- when -- why -- how

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1 can I express this clearly?

2 The QD dosing was still a possibility

3 for all indications. I was not -- I couldn't --

4 until one had the data, one could not be one

5 hundred percent sure that QD dosing would not be

6 available for all indications. On the other hand,

7 I could not exclude the fact that the QD dosing

8 would be the -- sorry. Let me -- I'm going around

9 in circles.

10 I couldn't exclude the fact that

11 QD dosing would be the -- would be present for all

12 indications. It was -- we were waiting to see.

13 Q. You were waiting to see?

14 A. The trials.

15 Q. You -- you wanted to see the results?

16 A. Correct. But it was still possible

17 that QD dos- -- QD dosing would be there for

18 the -- for the CAP and the sinusitis.

19 Q. It was possible?

20 A. Yes.

21 Q. In your own mind, is there a difference

22 between something that's possible and something

23 that's expected?

24 A. I think one's -- oh, it's words.

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1 MR. PHILLIPS: Well, I'm going to object to
2 the extent you're asking him to interpret the
3 document --

4 MR. ZWICKER: I'm asking -- I didn't.

5 I didn't. I asked him --

6 MR. PHILLIPS: Well, then, you're asking him
7 for some sort of English language lessons?

8 MR. ZWICKER: No. I'm asking him in his --
9 I'll repeat the question. He can answer it.

10 BY MR. ZWICKER:

11 Q. In your own mind, is there a difference
12 between something that's possible and something
13 that's expected?

14 MR. PHILLIPS: Well, I'll object to the
15 extent you're asking him to interpret the term
16 "expected" as it's used in this document as
17 calling for speculation and lacking in foundation.

18 Could you please not lean toward the
19 witness, counsel.

20 MR. ZWICKER: I'm not imposing on him.

21 MR. PHILLIPS: I think you are. Can you lean
22 back.

23 MR. ZWICKER: Well, he hasn't said so. No.
24 I'm -- I'm -- I'm not -- I have kept my space.

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1 Greg, I think you're interfering. I --
2 there's a question pending. Let him answer the
3 question.

4 MR. PHILLIPS: I don't think I'm interfering,
5 counsel.

6 BY THE WITNESS:

7 A. Sir, from my perspective, I don't know
8 what was meant by "expected" in this particular
9 paragraph. I would have to postulate, and I don't
10 want to postulate on someone else's written word.

11 For me, "possibilities" mean that
12 they -- that one would keep an open mind as to
13 what the data said.

14 BY MR. ZWICKER:

15 Q. My question to you was only in your
16 mind, is there a difference between something
17 that's possible and something that's expected?

18 A. I don't know.

19 MR. PHILLIPS: Again, I'll object to the
20 extent that you are asking him or trying to get
21 him to imply that he can interpret the term
22 "expected" as it's used in this document --

23 MR. ZWICKER: You're coaching.

24 MR. PHILLIPS: -- as lacking in foundation or

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1 speculation. I'm not counseling him, counsel, and
2 I object to your characterization.

3 BY MR. ZWICKER:

4 Q. Can you answer the question?

5 A. From my perspective, I may use the
6 words in different contexts. I do not know the
7 person who wrote this document, how they used the
8 words.

9 MR. PHILLIPS: Joe, you're being --

10 MR. ZWICKER: Let's take a break.

11 THE VIDEOGRAPHER: This will now conclude
12 Videotape No. 3, and we are going off the record
13 at 2:15 p.m.

14 (WHEREUPON, a recess was had from
15 2:15 p.m. until 2:22 p.m.)

16 THE VIDEOGRAPHER: We are now back on the
17 record, and the time is 2:22 p.m., and this is
18 Videotape No. 4 of the deposition of Dr. Stanley
19 Bukofzer on May 9th, 2007.

20 Counsel?

21 BY MR. ZWICKER:

22 Q. Dr. Bukofzer, turn to page 4 of
23 Bukofzer Exhibit No. 9; and at the very top,
24 you see a section called "Scientific Rationale for

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1 (WHEREUPON, said document was
2 marked Bukofzer Deposition Exhibit
3 No. 13, for identification, as of
4 5/9/07.)

5 THE WITNESS: Thank you.

6 MR. ZWICKER: Before the witness is Bukofzer
7 Exhibit No. 13, which is a memorandum dated
8 May 2nd, 2001 to Stan Bukofzer and others
9 regarding a First Call Report, FDA Advisory Panel
10 recommendations on Ketek.

11 BY MR. ZWICKER:

12 Q. Dr. Bukofzer, could you review this
13 document, and let me know when you're done.

14 (Short pause.)

15 BY THE WITNESS:

16 A. Yes, I've seen this document. Yes,
17 I've seen this document.

18 BY MR. ZWICKER:

19 Q. Do you recognize it?

20 A. Yeah, I recognize the document.

21 I mean, I --

22 MR. PHILLIPS: Counsel --

23 THE WITNESS: You know --

24 MR. PHILLIPS: Excuse me. No, no. Please

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1 were just putting our strategies together at that
2 time.

3 Q. Do you recall any conversations with
4 John Leonard on the subject of this memorandum?

5 A. No, not directly. I don't recall any
6 specific conversations. I have no doubt that had
7 I seen him at a meeting or something, he would
8 have said, "Have you seen the Ketek" or "What did
9 you think of it?" But I don't recall any
10 specific, you know, particular conversations.

11 Q. The memo says:

12 "I'm sure you had a chance to see
13 the FDA Advisory Panel recommendations
14 on Ketek. The FDA is clearly taking a
15 hard line (as we expected) on the safety
16 issues associated with Ketek."

17 See that?

18 A. Yes, I see that.

19 Q. Speaking only for yourself, did you
20 expect the FDA to take a hard line for safety
21 issues associated with Ketek?

22 A. Speaking for myself, I expected the
23 standards to be high in terms of the data that we
24 needed to supply the FDA to convince them that

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1 there would be no safety issue -- or not no safety
2 issues but that there would be no QT or liver
3 abnormality issues.

4 Q. You said you expected the standards to
5 be high, correct?

6 A. Correct.

7 Q. How high?

8 A. Well, that's always the question.

9 There was no defined -- there was no defined
10 target that you were moving towards. One of the
11 things, as I men- -- as I had mentioned earlier,
12 was that we as a company were trying to understand
13 the -- the standards that we would have to apply
14 to our clinical tr- -- or to our trials for QT
15 interval. And I think that's some of the -- that
16 was what Dr. Verlinden was trying to reference in
17 her e-mail.

18 And I think we also understood that --
19 or I understood that one was going to have to make
20 a decision regarding whether we needed to have a
21 reread of all our QT -- all our -- all the QT
22 intervals in all our clinical studies. I finally
23 made that decision, that we actually spent a lot
24 of money to try to get it -- to try and make the

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1 data to the highest possible standard that we
2 could.

3 Q. So speaking only for yourself, you
4 weren't surprised that the FDA took a hard line
5 with respect to safety issues for Ketek?

6 MR. PHILLIPS: Objection, calls for
7 speculation.

8 BY THE WITNESS:

9 A. I can't speculate what the FDA did.
10 I know that this was an advisory. The Advisory
11 Panel -- I don't know if you understand Advisory
12 Panels, but essentially, the FDA -- someone from
13 the FDA presents data, and then the advisors --
14 someone from the company can present data, and
15 then the advisors discuss it.

16 This was an Advisory Committee. The
17 FDA can accept -- it doesn't have to accept the
18 recommendations of the advisors.

19 BY MR. ZWICKER:

20 Q. For purposes of QTc, what did Abbott do
21 in response to Ketek --

22 MR. PHILLIPS: In response --

23 BY MR. ZWICKER:

24 Q. (Continuing) -- or the Ketek advisory?

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1 A. I -- our legal counsel at Abbott,
2 Mr. Peter Witty, informed me what a 30(2)(b)
3 deposition was, but not specifically about the
4 product.

5 Q. But my question is -- and maybe you've
6 just answered it -- is, did you talk to other
7 persons substantively involved with the compound?

8 A. No.

9 MR. ZWICKER: Let's mark this next exhibit.

10 (WHEREUPON, said document was
11 marked Bukofzer Deposition Exhibit
12 No. 23, for identification, as of
13 5/9/07.)

14 THE COURT REPORTER: 23.

15 THE WITNESS: Thank you.

16 MR. ZWICKER: Before the witness is a Notice
17 of Deposition dated March the 30th, 2007.

18 BY MR. ZWICKER:

19 Q. Dr. Bukofzer, did you review topic
20 No. 3 of Exhibit 23 in preparation for your
21 deposition today?

22 A. Topic No. 3? That's --

23 Q. I'll read it to you. It says:

24 "Abbott's knowledge and belief

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1 A. Sorry. Can you restate the question

2 because --

3 Q. Yeah. I'll restate it.

4 A. -- it doesn't make sense.

5 Q. Yeah. I'll restate it.

6 As of March the 13th, 2001, Abbott is

7 evaluating whether Phase 3 clinical trials for 773

8 are going to be dosed at 150 milligrams once a day

9 or twice a day, correct?

10 A. For which indications?

11 Q. As of March 13th, 2001, for all

12 indications. Is that true?

13 A. I think the commercial intent was to

14 dose all indications at a QD dose at that

15 particular time.

16 Q. As of March 13th, though, Abbott had

17 not decided definitively whether to dose all

18 indications at once-a-day dosing, correct?

19 A. Further data was deemed to be necessary

20 to make that final decision.

21 Q. And you agree with me that the decision

22 regarding whether indications for 773 would be

23 dosed once a day or twice a day had an impact on

24 the potential profitability of 773, correct?

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1 A. I think that there was preference for
2 the once-daily dosing from a commercial
3 perspective.

4 Q. Preference because once-daily dosing,
5 in Abbott's view, made 773 potentially a more
6 valuable compound?

7 A. Because once-daily dosing was where
8 most of the marketplace was believed to be heading
9 and, therefore, twice-daily dosing was perceived
10 by some to be -- to be less convenient.

11 Q. So once-daily dosing, in Abbott's view,
12 was an issue that would impact differentiation
13 from competitors in the market, correct?

14 MR. PHILLIPS: Objection.

15 I'm sorry. Could you read the question
16 back? I'm not sure I heard it.

17 MR. ZWICKER: Let me -- let me rephrase it.

18 MR. PHILLIPS: Okay.

19 BY MR. ZWICKER:

20 Q. So once-daily dosing, in Abbott's view,
21 could conceivably differentiate 773 from other
22 products in the market, correct?

23 A. No.

24 Q. Okay. Abbott viewed once-daily dosing

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1 as the emerging market standard for new
2 anti-infectives?

3 MR. PHILLIPS: Objection, vague as to what
4 you mean by "emerging market."

5 BY THE WITNESS:

6 A. Can you rephrase that? I don't know
7 how Abbott viewed -- or I don't know what -- what
8 you mean by "emerging market standard."

9 BY MR. ZWICKER:

10 Q. You testified that once-daily dosing
11 was where the marketplace was believed to be
12 headed, correct?

13 A. Correct.

14 Q. So that Abbott believed on March 13th,
15 2001 that an inability to achieve once-daily
16 dosing would disadvantage Abbott in the
17 marketplace, fair?

18 A. In the U.S. marketplace, consumers
19 would prefer a QD dose.

20 Q. As of March 13th, 2001, had Abbott
21 quantified in any way the impact on value of
22 once-daily dosing as opposed to twice-daily
23 dosing?

24 A. I'm not aware of specific

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1 quantification at that particular time.

2 Q. And as of March the 13th, 2001, Abbott

3 was still evaluating data that would allow it to

4 select once-daily or twice-daily dosing, correct?

5 MR. PHILLIPS: For all indications?

6 MR. ZWICKER: For all indications.

7 BY THE WITNESS:

8 A. I don't believe that to be correct.

9 BY MR. ZWICKER:

10 Q. For ABS and CAP indications?

11 A. For ABS and CAP indications, that would

12 be true.

13 Q. As of March the 13th, 2001, Abbott

14 believed that the ability to make a successful

15 resistance claim to the FDA would advance its

16 probabilities of FDA approval, is that right?

17 A. No, I don't think that that's correct.

18 Q. Did Abbott believe on March 13th, 2001,

19 that a resistance claim would have commercial

20 advantages?

21 A. I think that Abbott believed that a

22 resistance claim would help differentiate the drug

23 from other unmarketed drugs, specifically

24 macrolides.

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1 Can we take two minutes? I'd like to

2 review my notes to see if I have any questions.

3 MR. ZWICKER: Okay.

4 THE VIDEOGRAPHER: We are now going off the

5 record at 6:09 p.m.

6 (WHEREUPON, a recess was had from

7 6:09 p.m. until 6:13 p.m.)

8 THE VIDEOGRAPHER: We are now back on the

9 record at 6:13 p.m.

10 Counsel?

11 EXAMINATION

12 BY MR. PHILLIPS:

13 Q. Dr. Bukofzer, I just have, I think, one

14 or two questions to follow up on what counsel

15 asked you.

16 On -- turning to Exhibit 16, please,

17 and you'll recall that counsel asked you a number

18 of questions about this ABT-773 Decision Analysis

19 Core Team presentation.

20 A. Yes, I do.

21 MR. ZWICKER: I just -- okay. I have it.

22 MR. PHILLIPS: I'm sorry. You have it now?

23 BY MR. PHILLIPS:

24 Q. Turning to page 4 of the document,

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1 which is Bates numbered 103194.UR, do you see

2 that?

3 A. I found that page.

4 Q. You have that?

5 A. I have.

6 Q. Dr. Bukofzer, the -- did you prepare

7 this slide?

8 A. I certainly did prepare part of this

9 slide.

10 Q. At the very top, it says:

11 "Ketek advisory defined new

12 regulatory standards influences

13 program size."

14 Do you see that?

15 A. I see that.

16 Q. Dr. Bukofzer, what did you mean with

17 the statement -- by that statement?

18 A. I think that it's important to

19 understand that the Ketek advisory was one of a

20 couple, maybe three, really watershed times in

21 learnings about this drug.

22 Specifically, the regulatory standard

23 that I was referring to here involves two aspects.

24 The one aspect is how many patients you needed at

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1 a particular dose in order to ensure that there
2 was adequacy in general for safety. And on -- and
3 as indicated here, there had been some questions
4 in -- by the -- I can't recall if it was a
5 committee or the FDA as to whether 3,200 patients
6 database total was adequate for the -- or for --
7 for Ketek. I think what we did know is, the way
8 the FDA had in the past been more concerned about
9 safety aspects, such as in the quinolone
10 antibiotics, they had wanted up to 6,000 patients.

11 Additionally, I think that we talked
12 previously about the resistance claim. And while
13 I wasn't surprised by the fact that Ketek had
14 not -- or there was not a positive feeling towards
15 a resistance claim based on the data that they had
16 supplied, the question was whether or not there
17 was adequacy in the number of samples that they
18 had presented.

19 And so this second part talks to the
20 factors, whether or not in our CAP patients in
21 particular, we would have to increase the size of
22 our trials. And why this is important is that
23 both of these, the size of the -- the overall size
24 of the database as well as the size of the CAP

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1 trials moving forward, were both pointing in the
2 direction that there would be more patients
3 necessary than perhaps we had planned in the past.

4 And that's got financial and time
5 implications associated with it, and that's why
6 we -- why it was such an important learning at
7 that particular time.

8 MR. ZWICKER: Move to strike as
9 nonresponsive.

10 MR. PHILLIPS: Thank you.

11 I have no other questions.

12 MR. ZWICKER: I have none.

13 THE WITNESS: Okay.

14 MR. ZWICKER: Thank you.

15 THE VIDEOGRAPHER: This will now conclude
16 today's testimony. This will conclude Videotape
17 No. 6, and we are going off the record at
18 6:16 p.m.

19

20 FURTHER DEPONENT SAITH NAUGHT.

21

22 (Time noted: 6:17 p.m.)

23

24

Bukofzer Deposition Exhibit 9

P's Exhibit IM

CONFIDENTIAL

ABT - 773

Descriptive Memorandum

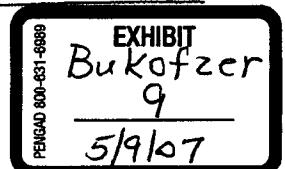
February 2001

Abbott Laboratories

CONFIDENTIAL
JH 008153

Descriptive Memorandum ABT - 773

CONFIDENTIAL



ABT-773**Opportunity Overview**

ABT-773 pertains to a promising new class of antibiotics known as ketolides. ABT-773 is likely to have activity against resistant strains of bacteria and will, therefore, compete effectively against currently marketed antibiotics. The compound is currently in Phase II/III trials. Phase III clinical trials began in Q4, 2000. ABT-773 has an expected U.S. launch date in Q1, 2004. Ex-U.S. launches are projected in 2004 for Europe and Japan.

Product features such as high efficacy, activity against resistant strains of bacteria and convenience should enable it to compete against both Zithromax and newer agents such as the quinolones. Dosing is expected to be once-a-day. A 5-day convenience pack at a competitive price will help maximize sales.

The US Market

The overall antibiotic market in the U.S. reached \$8.9 billion in sales in 1999. The tab/cap segment is the largest; sales in 1999 were \$6.7 billion. The I.V. and oral suspension segments are comparatively smaller; total sales topped \$2.1 and \$1.1 billion, respectively.

Tab/cap and oral suspension prescription volume had been declining 1.2% per year in the period of 1995-1998, due to more appropriate prescribing in the face of increasing resistance. However, total tab/cap prescription volume recovered in 1999 and grew 6.3%. Even in the face of negative pressure on antibiotic use, dollar sales in the U.S. have continued to increase, particularly in the tab/cap market. This is due to the trend of replacing relatively low-cost generic agents with higher priced premium antibiotics. The market is willing to bear higher costs for agents that satisfy unmet needs. The I.V. market has grown slightly in terms of sales, also being driven largely by the replacement of generic agents with more costly branded agents.

Macrolides, largely fueled by the gains of Zithromax, have seen significant growth in terms of both prescriptions and sales. Zithromax prescriptions far outnumber those of other competitors, while its sales have nearly surpassed those of the sales leader, Cipro. Historically, quinolones saw relatively limited use for community respiratory tract infections (RTIs) because of poor Gram-positive coverage and sub-optimal adverse event profiles. Newer quinolones such as Levaquin have been successful in achieving more widespread use by virtue of its improved activity and adverse event profile. Levaquin currently accounts for approximately 30% of the quinolone market share. It is anticipated that recent quinolone introductions (Avelox, Tequin) will build upon the RTI momentum established by Levaquin. The growth of the macrolide and quinolone classes has come largely at the expense of cephalosporins and generic agents such as erythromycin and penicillin.

The following table shows 1999 tab/cap sales and prescriptions by class/product:

	Sales			TRxs		
	Sales (\$MM)	Share	CAGR ₁₉₉₅₋₉	TRxs (MM)	Share	CAGR ₁₉₉₅₋₉
Penicillins	\$148.5	2.5%	-1.6%	52.5	23.7%	-5.6%
Cephalosporins	\$880.5	17.2%	-5.8%	37.9	17.1%	-3.5%
Cipro	\$383.9	6.7%	1.8%	5.0	2.3%	-1.0%
Cefix	\$108.7	2.0%	22.5%	2.7	1.2%	+1.3%
Other	\$408.2	7.1%	-14.7%	30.1	13.5%	-4.5%
Ext. Sales: Macrolides	\$1,985.8	27.9%	18.9%	36.1	16.1%	30.4%
Bisn	\$590.5	12.1%	6.7%	11.3	5.1%	1.2%
Zithromax	\$897.1	16.6%	42.1%	24.4	11.0%	41.9%
Other	\$34.9	0.5%	21.6%	0.4	0.2%	33.0%
Quinolones	\$1,622.1	29.4%	17.6%	24.0	10.8%	31.7%
Cipro	\$902.5	16.8%	8.3%	14.1	6.4%	5.1%
Levaquin	\$525.4	9.3%	N/A	7.0	3.1%	NA
Other	\$190.2	3.5%	-6.2%	8.0	1.3%	-6.4%
Aztreonam	\$778.1	13.8%	17.8%	10.7	4.9%	31.8%
Other Classes	\$590.5	10.3%	-1.1%	60.4	27.3%	-1.1%
TOTAL TAB/CAP	\$6,715.4	100.0%	6.9%	221.5	100.0%	8.1%

U.S. Market Projections

Resistance to antibiotics is likely to increase, creating opportunities for new agents with activity against resistance. Physicians will be urged to choose agents with an appropriate spectrum of activity relative to the infection being treated. Resistance will increasingly become part of the promotional mix for emerging agents. The ability of an agent to treat resistant strains and the real or perceived ability to slow or prevent resistance development (mutation prevention concentration, low mutation frequency, structure-activity relationships, etc) may confer competitive advantage to such agents.

- Quinolones, which historically have seen limited use in community-acquired respiratory infections, will become a significant class in this segment as new agents from this class are launched that specifically target RTIs.
- The market will become more competitive as new agents enter both the community segment (ketolides, quinolones) as well as the nosocomial segment (oxazolidinones, streptogramins, eveninomycins, peptides, others).
- Several key branded antibiotics will lose patent exclusivity over the next three to five years. This may create an opportunity in the pediatric market as the top three pediatric brands (Augmentin, Cefzil, Zithromax) are among those losing patent exclusivity.

Antiviral influenza and cold therapeutics, as well as an increasing number of antibacterial vaccines may have a negative impact on antibiotic prescriptions.

The Ex-U.S. Market

Ex-U.S. sales of antibiotics totalled \$11.7 billion in 1999. Tab/cap represents the largest segment, with sales of \$9.4 billion from 770 million total prescriptions. Total Rx growth has been flat, with a 1996-99 CAGR of 0.5%. The use of antibiotics is predicted to slowly decline due to more judicious use of antibacterials in the face of increasing bacterial resistance.

Ex-U.S., the quinolone class accounted for 8% of total tab/cap market prescriptions (62 million Rxs) and 13% of sales (\$1.2 billion). Ciprofloxacin is the market leader ex-U.S. with approximately 47% of the quinolone market Rxs (29 million Rxs) and 44% (\$530MM) of sales. Levofloxacin launched in many European markets in 1998/1999 and holds approximately 14% Rx share of the European quinolone market and 0.8% of the overall tab/cap market. Although grepafloxacin and trovafloxacin also launched in some European countries in 1999, both products were recently pulled from the market due to liver toxicity and other complications. Moxifloxacin launched in Germany in Q4 1999, but has not yet been approved in other markets. In Japan, levofloxacin launched in 1994 and still commands a 65% Rx share of the quinolone market and 10% of the Japanese tab/cap market overall. Japan accounts for approximately 80% of ex-U.S. levofloxacin sales (\$370MM).

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Scientific Rationale for ABT-773

The likely profile of ABT-773 justifies further development:

- ABT-773 pertains to a new class of antibiotics.
- Good activity against resistant Gram + organisms, particularly macrolide-resistant *S. pneumoniae*.
- Convenience, safety, and tolerability profile competitive with Z-pak.
- Oral Suspension and I.V. forms enabling penetration into pediatrics and hospital segments.

Clinical Studies

The safety and efficacy of ABT-773 in AECB were studied in a multi-center Phase II clinical trial conducted between January and April of 1999. Dosing regimens of 100mg TID and 200mg TID were tested. Of the 169 enrolled patients, 159 were clinically evaluable and 96 were both clinically and bacteriologically evaluable. The following chart summarizes the results.

Bacterial Eradication	ABT-773 100mg TID	ABT-773 200mg TID	Overall Eradication
<i>S. pneumoniae</i>	100% (13/13)	90% (9/10)	96% (22/23)
<i>M. catarrhalis</i>	100% (5/5)	100% (7/7)	100% (13/13)
<i>H. influenzae</i>	98% (23/24)	92% (24/26)	92% (47/50)
<i>H. parainfluenzae</i>	100% (5/5)	88% (7/8)	93% (13/14)

Clinical Response	ABT-773 100mg TID	ABT-773 200mg TID
Cure	95% (77/80)	92% (73/79)
Failure	4% (3/80)	8% (6/79)

Clinical and Bacterial Response	ABT-773 100mg TID	ABT-773 200mg TID
Cure	95% (45/48)	94% (45/48)
Failure	4% (2/48)	6% (3/48)

Adverse Events	ABT-773 100mg TID	ABT-773 200mg TID	Overall
Toile Perversion	5% (4/84)	6% (7/69)	6.5% (11/153)
Dizziness	11% (9/84)	9% (6/69)	8% (14/153)
Nausea	2% (2/84)	2% (2/69)	2% (4/153)
Abdominal Pain	1% (1/84)	2% (2/69)	2% (3/153)
Headache	2% (2/84)	1% (1/69)	2% (3/153)
Rash	2% (2/84)	1% (1/69)	2% (3/153)
Dyspepsia	2% (2/84)	—	1% (2/153)
Elow. Liver Funct. Test	1% (1/84)	1% (1/69)	1% (2/153)
Fever	—	2% (2/69)	1% (2/153)

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The safety and efficacy of ABT-773 in AECB were studied in a multi-center Phase IIb clinical trial from October 1999 to March 2000. Doses of 150mg QD, 300mg QD, and 600mg QD were tested. Of the enrolled subjects, 342 were clinically evaluable, and 169 were both clinically and bacteriologically evaluable. The following chart summarizes the results.

Bacterial Eradication	ABT-773 150mg QD	ABT-773 300mg QD	ABT-773 600mg QD	Overall Eradication
<i>S.pneumoniae</i>	83% (10/12)	90% (9/10)	100% (13/13)	91% (32/35)
<i>M.catarrhalis</i>	80% (8/10)	92% (12/13)	91% (10/11)	88% (30/34)
<i>H. Influenzae</i>	94% (17/18)	89% (17/19)	83% (19/23)	86% (53/60)
Clinical Response				
Cure	87% (98/113)	90% (105/117)	80% (101/112)	
Failure	13% (15/113)	10% (12/117)	10% (11/112)	
Clinical & Bacteriological Response				
Cure	84% (42/50)	88% (49/50)	94% (59/63)	
Failure	16% (8/50)	12% (7/56)	6% (4/63)	
Adverse Events				
Taste Perversion	5% (4/84)	19% (25/129)	29% (37/129)	17% (66/384)
Diarrhea	13% (16/126)	12% (15/129)	21% (27/129)	15% (58/384)
Nausea	7% (9/128)	13% (17/129)	30% (38/129)	17% (64/384)
Vomiting	2% (3/126)	3% (4/122)	11% (14/129)	6% (21/384)
Nausea & Vomiting	0 (0/126)	<1% (1/128)	4% (6/129)	2% (6/384)
Abdominal Pain	4% (5/126)	4% (5/129)	4% (5/129)	4% (18/384)

The safety and efficacy of ABT-773 in Acute Bacterial Sinusitis (ABS) were studied in a multi-center Phase IIb clinical trial conducted from October 1999 to March 2000. Dosing regimens of 150mg QD, 300mg QD, and 600mg QD were tested. Of the 292 enrolled subjects, 246 were clinically evaluable. The following chart summarizes the results.

Bacterial Eradication	ABT-773 150mg QD	ABT-773 300mg QD	ABT-773 600mg QD	Overall Eradication
<i>S.pneumoniae</i>	9/3	8/8	9/12	20/23
<i>M. catarrhalis</i>	8/9	3/4	4/4	15/17
<i>H. influenzae</i>	3/5	7/7	5/7	15/19
<i>S.aureus</i>	1/1	1/1	3/4	5/6
Clinical Response				
Cure	89% (70/79)	83% (70/84)	71% (59/83)	
Failure	11% (9/79)	17% (14/84)	29% (24/83)	
Adverse Events				
Taste Perversion	1% (1/97)	14% (14/96)	27% (28/97)	14% (41/292)
Diarrhea	6% (6/97)	6% (6/96)	17% (16/97)	10% (28/292)
Nausea	3% (3/97)	12% (12/96)	26% (26/97)	14% (40/292)
Vomiting	1% (1/97)	8% (8/96)	17% (16/97)	8% (23/292)

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The safety and efficacy of ABT-773 in community-acquired pneumonia (CAP) were studied in a multi-center Phase IIb clinical trial from October 1999 to March 2000. Dosing regimens of 300mg QD and 600mg QD were tested. Of the 187 enrolled subjects, 1248 were clinically evaluable, and 15 were both clinically and bacteriologically evaluable. The following chart summarizes the results.

Bacterial Eradication	ABT-773 300mg QD	ABT-773 600mg QD	Overall Eradication
<i>S. pneumoniae</i>	87% (13/15)	100% (7/7)	91% (20/22)
<i>M. catarrhalis</i>	75% (6/8)	50% (2/4)	67% (8/12)
<i>H. influenzae</i>	100% (5/5)	72% (13/18)	81% (22/27)
<i>M. pneumoniae</i>	93% (13/14)	93% (14/15)	93% (27/28)
<i>C. pneumoniae</i>	95% (19/20)	79% (19/24)	86% (38/44)
<i>L. pneumomiae</i>	100% (3/3)	100% (2/2)	100% (5/5)
Clinical Response			
Cure	92% (72/78)	80% (58/70)	
Failure	8% (6/78)	20% (14/70)	
Clinical & Bacterial Response			
Cure	92% (54/59)	82% (47/57)	
Failure	8% (5/59)	18% (10/57)	
Adverse Events			
Taste Perversion	17% (16/95)	26% (24/92)	21% (40/187)
Diarrhea	14% (13/95)	19% (17/92)	18% (30/187)
Nausea	12% (11/95)	22% (20/92)	17% (31/187)
Vomiting	10% (9/95)	15% (14/92)	12% (23/187)

• Appendix 1

Key Emerging Competitors

Generic	Brand	Company	Class	Status
moxifloxacin	Avelox	Bayer	Quinolone	Approved by FDA 12/13/00
gatifloxacin	Tequin	BMS	Quinolone	Approved by FDA 12/21/00
gemifloxacin	Factive	SKB	Quinolone	Filed NDA 12/15
T-3811	TBD	BMS/Toyama	Quinolone	Phase I
telithromycin	Ketek	Aventis	Ketolide	Filed NDA 3/00
linezolid	Zyvox	Pharmacia	Oxazolidinone	Approved by FDA Q2 '00

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Bukofzer Deposition Exhibit 13

P's Exhibit JA



JEFFREY M. LEIDEN, M.D., Ph.D
EXECUTIVE VICE PRESIDENT,
PHARMACEUTICALS AND
CHIEF SCIENTIFIC OFFICER

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FAX: (847) 937-2632

May 2, 2001

To: Stan Bukofzer

John Leonard

~~Eugene Sim~~

cc: Bill Dempsey

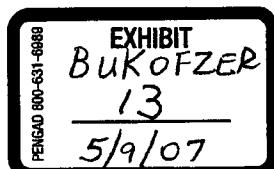
Arthur Higgins

Re: First Call Report

I'm sure you had a chance to see the FDA Advisory Panel recommendations on Ketek. The FDA is clearly taking a hard line (as we expected) on the safety issues associated with Ketek. This obviously makes it essential for us to re-evaluate our strategy with regard to the safety, particularly cardiovascular safety in our 773 trials. In this regard, I would appreciate it if Stan and Eugene put together a presentation for John, Arthur, Bill and myself on our proposed approach for dealing with these safety issues with 773.

I look forward to hearing your suggestions.

Jeff



14:44am EDT 27-Apr-01 Morgan Stanley/DW (Baum, Andrew) MORGAN SUMMARY AVEP.PA
 Aventis: Lame US Recommendation for Ketek. Delay Possible

Europe: France

April 27, 2001

Company Update

Aventis: Lame US Recommendation for Ketek. Delay Possible

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Paul Mann +44 20 7513 8273

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-- FDAAC RECOMMENDED KETEK FOR ONLY 1 OUT OF 3 PROPOSED INDICATIONS
 No recommendation for use in acute bronchitis or sinusitis. In
 addition, insufficient evidence of unique activity in penicillin and
 erythromycin resistant disease. Major erosion of potential marketing
 advantage.

- SAFETY IS THE REAL STICKING POINT

Panel needs more data. Concerned over cardiovascular risk and liver
 toxicity especially in at risk patients. No support for use in
 children. Panel propose "black box", more trials or monitoring.

- DELAY LIKELY WE BELIEVE. CURRENT ESTIMATE \$1BN IN 2007 - 12% OF
 SALES GROWTH

We sense that panel wanted to be more positive but lacked data. We
 suspect AVE may chose to delay and run safety trial, rather than launch
 a drug with an unattractive set of claims. Estimates under review.

OUTPERFORM-V

Price (Apr 25, 2001): Eu84.00

Price Target: Eu100.00

52-Week Range: Eu95.40 - 59.70

ADR Price, Target: \$75.10, 89

FY ending	2000PF	2001E	2002E	2003E	December:
EPS (Eu)	1.50	1.85	2.52	3.18	
CEPS (Eu)	3.25	3.69	4.49	5.25	
Revenue (Eum)	16,091	17,090	18,615	20,294	
Net Income (Eum)	1,172	1,445	1,970	2,490	
P/E	56	45.4	33.4	26.4	
P/CE	25.8	22.8	18.7	16.0	
EV/EBITDA	15.6	13.5	11.6	10.1	
Curr. Yield (%)	0.5	0.7	0.9	1.2	

Market Cap (US\$b, Eub)	58, 65
Enterprise Value (Eum)	60,338
Return on Equity (12/00) (%)	N/A
L-T Est. EPS Grth. ('02 - '07) (%)	11.5'07) (%)
Book Value (Eum)	9,936.8
1, 3, 12-mth Rel. Perf (%)	-7, 8, 48
P/E to Growth	2.90
Shares Outstanding (m)	781.0

ADR Data - Ords	2000A	2001E	2002E	2003E	per ADR: 1.00
EPADR (US\$)	1.35	1.67	2.27	2.86	

-- FIRST CALL --

P/E	56	45.4	33.4	26.4
CEPADR (US\$)	2.93	3.32	4.04	4.73
P/CE	25.8	22.8	18.7	16.0
Curr. Yield (%)	0.5	0.7	0.9	1.2
Exch Rate (US\$/Eu)	0.90	0.90	0.90	0.90

E = Morgan Stanley Dean Witter Research Estimates

Company Description

Aventis was formed in December 1999 through the merger of Hoechst's and Rhone-Poulenc's Life Sciences businesses. Aventis is the largest Life Sciences company in the world, with leading positions in both Pharmaceuticals and Agriculture. Sales in 1999 totalled Eu20.5 billion (\$20 billion), with the pharmaceutical's contributing 75% of the Life Sciences sales and 83% of operating profits. Late recommendation for Ketek Investment summary and conclusion: The FDA Advisory Committee last night gave Aventis's new antibiotic Ketek a far inferior set of claims than anticipated by the market, and far narrower than the recent recommendation by the European authorities, the CPMP. Aventis approached the FDA advisory committee with a toned down set of claims compared to the CPMP, dropping the treatment of tonsillitis and acute pharyngitis. Three key claims were targeted, community acquired pneumonia, acute exacerbation of chronic bronchitis and acute sinusitis. All five claims were recommended in EU by the CPMP. FDAAC votes yes for pneumonia only In stark contrast, the FDA rejected bronchitis and acute sinusitis by a vote of 10/0 and 8/2 respectively. Use in community acquired pneumonia was approved by a vote of 7/3. However, even in pneumonia, the drug was not recommended for its key competitive advantages- the use in pneumonia caused by organisms resistant to existing antibiotic penicillin and erythromycin. The FDA typically follows the advice of the advisory panel in 10/11 cases. The commercial impact of this inferior outlook will be substantial, in our view. We had anticipated 2007 sales of \$1bn in 2007, assuming the drug is approved on the back of these recommendations, we would be looking to reduce our forecasts by 50% or so. On our current numbers, Ketek contributes 11.4% of our incremental revenue growth 02-07. A revised forecast would reduce the revenue growth rate from 7.3% to around 6.8%. Safety is main concern; more data needed. The key concerns of the panel were safety given the evidence that Ketek is associated with QT prolongation in at risk patients, and potential for adverse hepatic events linked to interaction between Ketek and other drugs. The key concern is that release of the drug onto the market without further safety data may pose a risk given : (i)safety profile (ii)proclivity of physicians to use the drug off label in other indications (iii)proclivity of physicians to use drug in chronic setting in indication of bronchitis, where safety has not been fully evaluated There was also a reticence to provide support for recommending the drugs in children between the ages of 12-18, again in contrast the rerecommendation of the CPMP. The panel suggested a number of solutions including that Aventis might consider carrying out safety trials prior to launching the drug in order to benefit from a superior label with a broader set of claims. This would clearly manifest into a delayed drug launch of approximately a year we believe. Alternatively, the panel were happy to recommend approval of Ketek just for community acquired pneumonia but with black boxes relating to hepatic and cardiovascular risks, and/ or necessity for cardio/ hepatic monitoring. Given the absence of any competitive advantage in regard to activity in resistant infections, this adverse labelling is likely to have a significant negative effect on potential usage. Delayed US launch possible? As a result of yesterdays meeting, we suspect that Aventis may decide to delay the US launch of Ketek and carry out further safety trials.

-- FIRST CALL --

In the hope of ensuring a competitive label to achieve the commercial goals it has indicated to the market (\$1 bn peak sales) We believe that ultimately Ketek is likely to fulfil close to our expectations given the panel views. However the onus is now on Aventis to deliver the necessary clinical data to satisfy the panel and facilitate approval of the drug with a competitive set of claims. Given the above we would use any over-reaction in the share price to add to positions in the stock. Rated Outperform. Target Price Eu100. V = More volatile. We estimate that this stock has more than a 25% chance of a price move (up or down) of more than 25% in a month, based on a quantitative assessment of historical data, or in the analyst's view, it is likely to become materially more volatile over the next 1- 12 months compared with the past three years. Stocks with less than one year of trading history are automatically rated as more volatile (unless otherwise noted). We note that securities that we do not currently consider "volatile" can still perform in that manner.

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-> End of Note <-

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P's Exhibit QM

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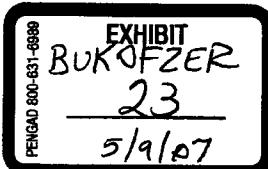
NO. 620 P. L

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF MASSACHUSETTS

JOHN HANCOCK LIFE INSURANCE)
COMPANY, JOHN HANCOCK)
VARIABLE LIFE INSURANCE)
COMPANY, and MANULIFE)
INSURANCE COMPANY (f/k/a)
INVESTORS PARTNER INSURANCE)
COMPANY),) CIVIL ACTION NO. 05-11150-DPW
Plaintiffs,)
v.)
ABBOTT LABORATORIES,)
Defendant.)

NOTICE OF DEPOSITION

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), plaintiffs John Hancock Life Insurance Company, John Hancock Variable Life Insurance Company, and Manulife Insurance Company (f/k/a Investors Partner Insurance Company) (collectively, "John Hancock") will take the deposition of defendant Abbott Laboratories on April 12, 2007 commencing at 9:30 a.m. at the offices of Levenfeld Pearlstein, LLC, 2 North LaSalle Street, Suite 1300, Chicago, Illinois, or such other location as may be mutually agreed to by the parties. Abbott shall designate, prepare and produce one or more knowledgeable officers, directors, or other representatives to testify on its behalf as to the topics set forth below.



MAY. 9. 2007 1:46AM CHUAIE HALL & STEWART 6112484000

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PLEASE TAKE FURTHER NOTICE that the deposition noticed above will be recorded stenographically, and through real-time court reporting, such as by LiveNote. The deposition also may be recorded by audio or video technology, such as videotape. The deposition will be taken before a notary public or other person authorized to administer oaths and will continue from day-to-day until completed, Saturdays, Sundays and holidays excepted.

Definitions

For purposes of this Notice, John Hancock adopts the "Uniform Definitions in Discovery Requests" contained in Local Rule 26.5. The following additional terms shall have the meanings set forth below:

1. "You," "your" and "Abbott" shall mean defendant Abbott Laboratories, its various corporate parents, subsidiaries, affiliates, subdivisions and departments, and any and all representatives, successors, assigns, officers, directors, employees, agents, attorneys or other persons or entities who have acted or purported to act for or on behalf of any of them.
2. "Abbott's Senior Management" shall mean the Abbott personnel who had or have overall responsibility, authority and accountability for managing Abbott's Global Pharmaceutical Research and Development organization and operations, including, without limitation, Miles D. White and the "Senior Management" referenced in Abbott Document No. ABBT0101924.
3. "John Hancock" shall mean collectively defendants John Hancock Life Insurance Company, John Hancock Variable Life Insurance Company, and Manulife Insurance Company (f/k/a Investors Partner Life Insurance Company), their various subsidiaries, affiliates, divisions and departments, and any and all representatives, successors, assigns,

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CHOATE HALL & STEWART 6172484000

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officers, directors, employees, agents, auditors, attorneys or other persons or entities who have acted or purported to act for or on behalf of any of them, including, without limitation, representatives of the StoneTurn Group.

4. The "Research Funding Agreement" shall mean the Research Funding Agreement by and between Abbott and John Hancock, dated as of March 13, 2001.

5. The "Program Compounds" shall have the meaning set forth in the Research Funding Agreement.

6. "Program Term" shall have the meaning set forth in the Research Funding Agreement.

7. "Regarding" shall have the same meaning as "concerning."

8. "Any" also shall mean "all," and "all" also shall mean "any."

9. "And" as well as "or" shall be construed both disjunctively and conjunctively to mean "and/or."

Topics Of Examination

1. Abbott's knowledge and belief concerning the prospects and condition (including safety, efficacy, scientific viability or commercial viability) of the Program Compound known as ABT-518 as of March 13, 2001.

2. Abbott's knowledge and belief concerning the prospects and condition (including safety, efficacy, scientific viability or commercial viability) of the Program Compound known as ABT-594 as of March 13, 2001.

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3. Abbott's knowledge and belief concerning the prospects and condition (including safety, efficacy, scientific viability or commercial viability) of the Program Compound known as ABT-773 as of March 13, 2001.

4. The knowledge and belief of each member of Abbott's Senior Management concerning the prospects and condition (including safety, efficacy, scientific viability or commercial viability) of the Program Compound known as ABT-518 as of March 13, 2001.

5. The knowledge and belief of each member of Abbott's Senior Management concerning the prospects and condition (including safety, efficacy, scientific viability or commercial viability) of the Program Compound known as ABT-594 as of March 13, 2001.

6. The knowledge and belief of each member of Abbott's Senior Management concerning the prospects and condition (including safety, efficacy, scientific viability or commercial viability) of the Program Compound known as ABT-773 as of March 13, 2001.

7. Abbott's valuation of, and methods for valuing (including, without limitation, any models used in such valuations) the Program Compound known as ABT-518 at any time from January 1, 2001 to the present.

8. Abbott's valuation of, and methods for valuing (including, without limitation, any models used in such valuations) the Program Compound known as ABT-594 at any time from January 1, 2001 to the present.

9. Abbott's valuation of, and methods for valuing (including, without limitation, any models used in such valuations) the Program Compound known as ABT-773 at any time from January 1, 2001 to the present.

10. Abbott's nominal or intended and reasonably expected spending on the Program Compound known as ABT-518 at any time from January 1, 2001 to the present.

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11. Abbott's nominal or intended and reasonably expected spending on the Program Compound known as ABT-594 at any time from January 1, 2001 to the present.

12. Abbott's nominal or intended and reasonably expected spending on the Program Compound known as ABT-773 at any time from January 1, 2001 to the present.

13. Abbott's reasons for discontinuing or terminating the development of the Program Compound known as ABT-518.

14. Abbott's reasons for discontinuing or terminating the development of the Program Compound known as ABT-594.

15. Abbott's reasons for discontinuing or terminating the development of the Program Compound known as ABT-773.

16. All communications among or between Abbott's Senior Management, at any time from January 1, 2000 to the present, regarding the prospects or condition (including safety, efficacy, scientific viability or commercial viability) of the Program Compound known as ABT-518.

17. All communications among or between Abbott's Senior Management, at any time from January 1, 2000 to the present, regarding the prospects or condition (including safety, efficacy, scientific viability or commercial viability) of the Program Compound known as ABT-594.

18. All communications among or between Abbott's Senior Management, at any time from January 1, 2000 to the present, regarding the prospects or condition (including safety, efficacy, scientific viability or commercial viability) of the Program Compound known as ABT-773.

. MAY. 9. 2007 / :4/AM

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19. All communications among and between senior Abbott's Senior Management, at any time from January 1, 2000 to the present, regarding the actual or potential discontinuation or termination of development of the Program Compound known as ABT-518.

20. All communications among and between senior Abbott's Senior Management, at any time from January 1, 2000 to the present, regarding the actual or potential discontinuation or termination of development of the Program Compound known as ABT-594.

21. All communications among and between senior Abbott's Senior Management, at any time from January 1, 2000 to the present, regarding the actual or potential discontinuation or termination of development of the Program Compound known as ABT-773.

22. The creation of, analysis reflected in, or actions taken by Abbott in connection with, the document attached hereto as Exhibit A as it pertains to the Program Compounds known as ABT-518, ABT-594 and ABT-773.

23. The creation of, analysis reflected in, or actions taken by Abbott in connection with, the document attached hereto as Exhibit B as it pertains to the Program Compounds known as ABT-518, ABT-594 and ABT-773.

24. The creation of, analysis reflected in, or actions taken by Abbott in connection with, the document attached hereto as Exhibit C as it pertains to the Program Compound known as ABT-594.

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NU. 02U R. 8

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COMPANY, JOHN HANCOCK VARIABLE
LIFE INSURANCE COMPANY, and
MANULIFE INSURANCE COMPANY
(f/k/a INVESTORS PARTNER INSURANCE
COMPANY)

By its attorneys,


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Date: March 30, 2007

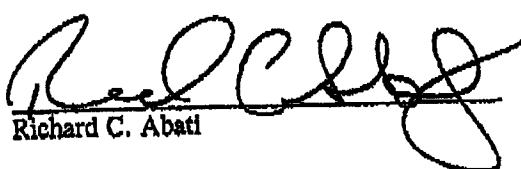
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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was served by electronic and overnight mail upon Peter E. Gelhaar, Esq., Donnelly, Conroy & Gelhaar, LLP, One Beacon Street, 33rd Floor, Boston, MA 02108, and Gregory D. Phillips, Esq., Munger, Tolles & Olson LLP, 355 South Grand Avenue, Los Angeles, CA 90071, on this 30th day of March, 2007.


Richard C. Abati

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